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SEP 15 2006

REMARKS

Claims 12-15, 17, 19, 20, 22-24, 27, 29, 31-34, 36-41, 43, 44, 46, 48-53, 56-61, 63, 64, 66, 68-70, 73-75, 77-80, 83-85, 87, 88, and 104-148 are pending and stand finally rejected. The Office Action states that claim 226 is also pending and rejected. Applicants believe the reference to claim 226 is mistaken and that claim 226 is not pending in the application.

In response to the Office Action, Applicants have amended claims 104, 114, 130, 139 and 145, and have cancelled all claims in the case except for claims 104 and 109-111; claims 114 and 119; claims 130 and 135-136; and claims 139 and 144-145. A complete listing of pending claims is attached, including a marked-up version of the amended claims, showing changes made.

All claim cancellations are made without prejudice. A continuation reissue application is being filed concurrent with this amendment to pursue the cancelled claims.

In addition, Applicants have offered new claims 149-168 in the present application to further define embodiments of the invention. Support for the amended and new claims is found in the specification as originally filed and as further described below.

Upon entry of the amendments, claims 104, 109-111, 114, 119, 130, 135-136, 139, 144-145, and 149-168 remain pending. Applicants respectfully request entry of the amendments.

**CONSIDERATION AFTER FINAL REJECTION**

Applicants respectfully submit that entry of the amendments and consideration of the following remarks is appropriate after a Final Rejection. As discussed below, the amendments place the claims in an allowable condition and do not require further examination. Independent claims 104, 114, 130, and 139, in particular, are amended to incorporate language specifically indicated by the Examiner as necessary to overcome rejections of record, and incorporate subject matter of dependent claims indicated as allowable. New claims 149-168 are dependent from these claims, and are literally supported by the specification, as further discussed herein. Applicants submit that these amendments address all issues of record, introduce no new matter and raise no new issues.

**OBJECTION TO THE APPLICATION UNDER 37 CFR § 1.172(a)**

To overcome an objection, a proper submission establishing ownership interest in the patent pursuant to 37 CFR § 1.172(a) is enclosed as part of the response to this Action. Specifically, a new paper, entitled "Statement Under 37 C.F.R. § 3.73(b)" is filed to designate Mr. Yoko Gen, the Chief Executive Officer of BMG Incorporated, as a person empowered to sign on behalf of the Assignee. As suggested in the Office Action, Applicants' attorney has signed the statement that BMG Incorporated is the Assignee and that the Chief Executive Officer of the Assignee is authorized to sign in behalf of BMG Incorporated. The paper "Assignee Consent Under 37 CFR § 1.172" was previously filed and signed by the Chief Executive Officer. A copy of the original signed document dated July 30, 2002 is attached for convenience.

Based on the above, Applicant respectfully requests that the objection to the Application under 37 CFR § 1.172(a) be withdrawn.

**CLAIM OBJECTIONS**

Claim 79 is objected to because of an informality. Claim 79 has been cancelled.

**REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

Claims 12-15, 38-41, 43, 44, 46, 48-52, 53, 56, 57, 58-61, 63, 64, 70, "7-75", 77-80, 83-85, 87, 88, 104-113, and 146 are rejected as failing to comply with the written description requirement. Applicants assume that "7-75" in the recitation of rejected claims is meant to refer to "73-75". In response, Applicants have cancelled all but claims 104 and 109-111. Accordingly, Applicants respectfully traverse the rejection as applied to the amended claims and request reconsideration.

Applicants have amended claim 104 (as well as claims 114, 130, and 139) to address an objection by the Examiner to the disclosure of irradiating a raw article "comprising" UHMWPE. Although claims 114, 130, and 139 are not listed in the Office Action as subject to the first paragraph rejection, Applicants note that they contain the same recitation of a raw article "comprising" UHMWPE as does claim 104.

The Office Action states that the recitation "raw article comprising UHMWPE" in claim 104 broadens the scope of subject matter originally described in the specification since it encompasses mixtures or blends of UHMWPE with other materials not described in the original specification. In response, Applicants respectfully submit that the original specification supports an invention described as a "raw article comprising UHMWPE". However, to advance prosecution, Applicants have amended claim 104

(and claims 114, 130, and 139) to recite that a "raw UHMWPE article" is irradiated to be in more literal conformance to language used in the specification.

Applicants submit that the amended claims reciting a "raw UHMWPE article" claim the same invention as the earlier offered claims reciting an "article comprising UHMWPE". Applicants respectfully submit these terms have no substantive distinction. Accordingly, the amended claims have the same scope as the original claims, and the amendment is not narrowing. In particular, Applicants respectfully submit that the invention is not limited by the current amendments to articles made of pure UHMWPE. Rather, the claimed invention encompasses compositions that persons of skill in the art would recognize as making up a raw UHMWPE article. Such compositions include, in addition to UHMWPE, at least such additives as antioxidants, lubricants, pigments, and other additives, as well as a variety of compatible polymeric materials that are commonly or occasionally used or could be used in commercial UHMWPE grades. Examples of the latter include blends with lower molecular weight polyolefins such as polyethylene, which can be added to decrease the flow viscosity and enable the grades to be molded or extruded.

Based on the discussion above, Applicants respectfully request the rejection under §112, first paragraph be withdrawn.

**REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

Claims 12-15, 17, 19, 20, 22-24, 26, 27, 29, 31-34, 36-41, 43, 44, 46, 48-53, 56, 57-61, 63, 64, 66, 68-70, 73, 74, 75, 77-80, 83-35, 87, 88, and 104-148 are rejected under 35 U.S.C. §112, second paragraph. Applicants respectfully traverse the rejection as applied to the amended claims and request reconsideration.

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Claims 1-103, 105-108, 112-113, 115-118, 120-129, 131-134, 137-138, 140-143, and 146-148 have been cancelled, mooted the rejections except as to claims 104, 109-111, 114, 119, 130, 135-136, 139, and 144-145.

Applicants have amended claims 104, 114, 130 and 139 to recite that the UHMWPE is slightly crosslinked by low dose irradiation, heated to its compression deformable temperature by heating at a temperature from its melting point -50°C to its melting point +80°C, compression deformed at its compression deformable temperature, and cooled while keeping the deformed state. The rejected claims dependent from the amended main claims also set forth the above steps.

As to claim 139, it is said to not be clear what steps are encompassed by the term "processing." Applicants respectfully submit that claim 139 as amended makes it clear that processing means steps carried out on the article after it is cooled while maintaining the deformed state. The amended claim is definite.

For the reasons discussed above, Applicants respectfully request that the §112 second paragraph rejections, as applied to the amended claims, be withdrawn.

#### **REJECTION UNDER 35 U.S.C. § 102**

Claims 12-15, 17, 19, 20, 22-24, 26, 27, 29, 31-34, 36, 37-41, 43, 44, 46, 48, 49, 51, 52, 58-61, 63, 64, 66, 68-70, 73-75, 77-80, 83, 84-88, 104-107, 112-131, 137-140, and 146-148 stand rejected under 35 U.S.C. § 102 as anticipated or obvious over the Sun et al reference (U.S. Pat. No. 5,414,049). Applicants respectfully traverse the rejection as applied to the amended claims and request reconsideration.

All of the rejected claims have either been cancelled or amended to recite a step of deforming an article by applying pressure at a compression deformable temperature.

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Such a teaching is absent from the Sun reference. Because the amended claims contain at least one limitation not disclosed or suggested in the reference, the claims are novel and non-obvious over the reference. For this reason, Applicants respectfully request that the rejections under 35 U.S.C. §102 be withdrawn.

#### **REJECTION UNDER 35 U.S.C. §103**

Claims 38-41, 43, 44, 46, 47, 50-53, 56, 57, 63, 64, 104-107, 111, 114-117, 122-125, 130-133, 135, 136, and 139-142 stand rejected under 35 U.S.C. §103(a) as obvious over the Sun et al. reference. Applicants respectfully traverse the rejection as applied to the amended claims and request reconsideration.

As with the §102 rejections discussed above, all of the claims rejected under §103 have either been cancelled or amended to recite a compression deformation step that occurs after the UHMWPE is irradiated. Because the Sun et al. reference does not disclose or suggest such a step, Applicants respectfully submit that the amended claims reciting those steps are not obvious. For these reasons, Applicants respectfully request that the rejection under §103, as applied to the amended claims, be withdrawn.

#### **ALLOWABLE SUBJECT MATTER**

Applicants note with appreciation that claims 108-111, 118-119, 134-136, and 143-145 would be allowable if rewritten to overcome the §112 rejections set forth in the Office Action, and to include all of the limitations of the base claim and the intervening claims. Applicants submit that this has been accomplished in the present amendment.

For example, Applicants have amended claim 104 to overcome the §112 rejection and incorporate the allowable subject matter of claim 108. Claims 109-111 depend from amended and allowable claim 104.

Similarly, Applicants have amended claim 114 to address the §112 issues and to incorporate the allowable subject matter of claim 118. Claim 119 depends from allowable claim 114.

In a similar manner, Applicants have amended claim 130 to address the §112 issues and to incorporate the allowable subject matter of claim 134. Claims 135 and 136 depend from allowable claim 130.

Finally, Applicants have amended claim 139 to overcome the §112 rejections and to incorporate the allowable subject matter of claim 143. Claims 144 and 145 depend from allowable claim 139.

#### **NEW CLAIMS 149-168**

New claims 149-168 are offered depending from the respective main claims and further define the invention:

claims 149-153 depend from allowable claim 104;

claims 154-158 depend from allowable claim 114;

claims 159-163 depend from allowable claim 130; and

claims 164-168 depend from allowable claim 139.

The new claims are clearly in an allowable condition because they depend from allowable main claims. No further examination is required. Support for the limitations embodied in these claims is found in the specification as follows:

149. (new) A method according to claim 104, wherein the <i>irradiation is gamma-irradiation.</i>	col. 3, lines 26-29: Every kind of high energy rays can be employed as the high energy ray to be irradiated, <i>for example a radioactive ray such as <math>\gamma</math>-ray or X-ray</i> , an electron beam, a neutron ray and the like.
150. (new) A method according to claim 104, wherein the raw UHMWPE article comprises <i>UHMWPE having a weight average molecular weight of 2 – 8 million.</i>	col. 3, lines 22-24: As the raw UHMWPE, one having a <i>weight-average molecular weight of 2 to 8 million</i> , preferably 5 to 7 million is used.
151. (new) A method according to claim 104, wherein the article comprises <i>UHMWPE having 0.1 – 10 crosslinking points per 1 molecular chain.</i>	col. 3, lines 25-39: The density of crosslinking is preferably such a very small degree that the crystallization is not prevented with ensuring a large elastic-deformation, for example <i>0.1 to 10</i> , particularly 1 to 2 <i>crosslinking points per one molecular chain.</i>
152. (new) A method according to claim 104, wherein the <i>irradiation dose is from 0.01 to 5.0 MR.</i>	col. 3, lines 62-65: <i>A preferable dose of irradiation (energy) is the dose to give the above-mentioned density of crosslinking and 0.01 to 5.0 MR</i> , preferably 0.1 to 3 MR in case of radioactive rays.
153. (new) A method according to claim 104, wherein the <i>compression deformable temperature is from 100°C to 130°C.</i>	col. 4, lines 5-14 The <i>compression-deformable temperature</i> of [sic] is a temperature of around or not less than the melting point of the crosslinked UHMWPE, and is concretely from the melting point minus 50° C. to the melting point plus 80° C. ... The compression-deformation can be carried out, however, at a <i>temperature of even around the melting point, for example 100° to 130° C.</i>
claims 154-158, depending from allowable claim 114	same as for claims 149-153
claims 159-163, depending from allowable claim 130	same as for claims 149-153
claims 164-168, depending from allowable claim 139	same as for claims 149-153

Applicants respectfully request passage of claims 149-168 to an allowable condition.

### CONCLUSION

For the reasons discussed above, Applicants believe that claims are in an allowable condition and respectfully request an early notice of allowance. In the alternative, Applicants respectfully request an Advisory Action stating whether the amendments can be entered and the remarks considered at this time. The Examiner is



encouraged to telephone the undersigned if that would be helpful in resolving any issues.

Respectfully submitted,

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**APPENDIX A****COMPLETE CLAIM LIST WITH MARKED UP VERSION OF AMENDED CLAIMS****LISTING OF CLAIMS**

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1.-103. (cancelled)

104. (twice amended) A method for making an ultra high molecular weight polyethylene (UHMWPE) article, for subsequent processing to make an artificial joint, comprising:

- (a) [Irradiating] crosslinking a raw UHMWPE article slightly with low dose irradiation [comprising UHMWPE]; and then
- (b) heating said irradiated article to a compression deformable temperature of from 50° C below the melting point of said article to 80° C above said melting point;
- (c) compression deforming the heated article; and then
- (d) cooling the article while maintaining the deformed state.

105-108. (cancelled)

109. (amended) A method according to Claim 104 [108], wherein pressure is applied during said heating step.

110. (amended) A method according to Claim 109, further comprising cooling said article and isothermally crystallizing said cooled article after said heating step.

111. (amended) A method according to Claim 110, wherein said Isothermal crystallizing comprises heating said article to a temperature of from around 100°C to 130°C for a period of from 1 hour to 20 hours.

112.-113. (cancelled)

114. (twice amended) A method for making an ultra high molecular weight polyethylene (UHMWPE) article which is suitable for subsequent processing to make an artificial joint, so as to improve the wear resistance properties of said article, comprising:

- (a) [irradiating] crosslinking a raw UHMWPE article slightly with low dose irradiation [comprising UHMWPE]; and then
- (b) heating said irradiated article to a compression deformable temperature of from 50° C below the melting point of said article to 80° C above said melting point;
- (c) compression deforming the heated article; and then
- (d) cooling the article while maintaining the deformed state.

115.-118. (cancelled)

119. (previously presented) A method according to claim 114, wherein pressure is applied during said heating step.

120.-129. (cancelled)

130. (twice amended) A method for making an ultra high molecular weight polyethylene (UHMWPE) article, for subsequent processing to make an artificial joint, comprising:

- (a) [irradiating] crosslinking a raw UHMWPE article [comprising UHMWPE] slightly with low dose irradiation; and then
- (b) heating the irradiated article to a compression deformable temperature by heating at a temperature from its melting point minus 50°C to its melting point plus 80°C;

- (c) applying pressure to said irradiated article at a deformation temperature;  
then
- (d) heating said irradiated article to a temperature of from around 100° C to 130° C for a period of at least 1 hour; and then
- (e) cooling the heated article while maintaining the deformed state.

131.-134. (cancelled)

135. (twice amended) A method according to Claim 130 [134], wherein said deformation temperature is between 50° C below the melting point of said article and said melting point.

136. (twice amended) A method according to Claim 130 [134], wherein said deformation temperature is from said melting point to 80° C above said melting point.

137.-138. (cancelled)

139. (twice amended) A method of making a component for an artificial joint comprising ultra high molecular weight polyethylene (UHMWPE), comprising:

- (a) [irradiating] crosslinking a raw UHMWPE article [comprising UHMWPE] slightly with low dose irradiation; and then
- (b) heating the irradiated article to a compression deformable temperature by heating at a temperature from its melting point minus 50°C to its melting point plus 80°C;
- (c) applying pressure to said irradiated article at a deformation temperature;
- (d) heating said irradiated article to a temperature of from around 100° C to 130° C for a period of at least 1 hour; and then
- (e) cooling the article while maintaining the deformed state; and then
- (f) [(c)] processing said article to make said component.

140.-143. (cancelled)

144. (twice amended) A method according to Claim 139 [143], wherein said deformation temperature is between 50° C below the melting point of said article and said melting point.

145. (twice amended) A method according to Claim 139 [143], wherein said deformation temperature is from said melting point to 80° C above said melting point.

146.-148. (cancelled)

149. (new) A method according to claim 104, wherein the irradiation is gamma-irradiation.

150. (new) A method according to claim 104, wherein the raw UHMWPE article comprises UHMWPE having a weight average molecular weight of 2 - 8 million.

151. (new) A method according to claim 104, wherein the article comprises UHMWPE having 0.1 – 10 crosslinking points per 1 molecular chain.

152. (new) A method according to claim 104, wherein the irradiation dose is from 0.01 to 5.0 MR.

153. (new) A method according to claim 104, wherein the compression deformable temperature is from 100°C to 130°C.

154. (new) A method according to 114, wherein the irradiation is gamma-irradiation.

155. (new) A method according to claim 114, wherein the raw UHMWPE article comprises UHMWPE having a weight average molecular weight of 2 - 8 million.

156. (new) A method according to claim 114, wherein the article comprises UHMWPE having 0.1 – 10 crosslinking points per 1 molecular chain.

157. (new) A method according to claim 114, wherein the irradiation dose is from 0.01 to 5.0 MR.

158. (new) A method according to claim 114, wherein the compression deformable temperature is from 100°C to 130°C.

159. (new) A method according to 130, wherein the irradiation is gamma-irradiation.

160. (new) A method according to claim 130, wherein the raw UHMWPE article comprises UHMWPE having a weight average molecular weight of 2 - 8 million.

161. (new) A method according to claim 130, wherein the article comprises UHMWPE having 0.1 – 10 crosslinking points per 1 molecular chain.

162. (new) A method according to claim 130, wherein the irradiation dose is from 0.01 to 5.0 MR.

163. (new) A method according to claim 130, wherein the compression deformable temperature is from 100°C to 130°C.

164. (new) A method according to 139, wherein the irradiation is gamma-irradiation.

165. (new) A method according to claim 139, wherein the raw UHMWPE article comprises UHMWPE having a weight average molecular weight of 2 - 8 million.

166. (new) A method according to claim 139, wherein the article comprises UHMWPE having 0.1 – 10 crosslinking points per 1 molecular chain.

167. (new) A method according to claim 139, wherein the irradiation dose is from 0.01 to 5.0 MR.

168. (new) A method according to claim 139, wherein the compression deformable temperature is from 100°C to 130°C.